REDUCED PRESSURE TREATMENT SYSTEM

by

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CROSS REFERENCES TO OTHER APPLICATIONS

This application claims the benefit of U.S. provisional application No. 60/407,783, filed on September 3, 2002, and U.S. provisional application No. 60/430,827, filed on December 4, 2002. The full disclosures of both provisional applications are incorporated herein by reference.

BACKGROUND

The present invention relates to an apparatus and a method for treating a wound by applying reduced pressure to the wound. In this context, the term "wound" is to be interpreted broadly, to include any body part of a patient that may be treated using reduced pressure.

The treatment of open or chronic wounds that are too large to spontaneously close or otherwise fail to heal has long been a troublesome area of medical practice. Closure of an open wound requires inward migration of surrounding epithelial and subcutaneous tissue. Some wounds, however, are sufficiently large or infected that they are unable to heal spontaneously. In such instances, a zone of stasis in which localized edema restricts the flow of blood to the epithelial and subcutaneous tissue forms near the surface of the wound. Without sufficient blood flow, the wound is unable to successfully fight bacterial infection and is accordingly unable to close spontaneously.

An initial stage of wound healing is characterized by the formation of granulation tissue

which is a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that forms the basis for subsequent epithelialization of the wound. Infection and poor vascularization hinder the formation of granulation tissue within wounded tissue, thereby inhibiting wound healing. It therefore becomes desirable to provide a technique for increasing blood circulation within wounded tissue to promote spontaneous healing and to reduce infection.

Another problem encountered during the treatment of wounds is the selection of an appropriate technique for wound closure during the healing process. Sutures are often used to apply force to adjacent viable tissue in order to induce the edges of a wound to migrate together and heal. However, sutures apply a closure force to only a very small percentage of the area surrounding a wound. When there is scarring, edema, or insufficient tissue, the tension produced by the sutures can become great causing excessive pressure to be exerted by the sutures upon the tissue adjacent to each suture. As a result, the adjacent tissue often becomes ischemic thereby rendering suturing of large wounds counterproductive. If the quantity or size of the sutures is increased to reduce the tension required of any single suture, the quantity of foreign material within the wound is concomitantly increased and the wound is more apt to become infected. Additionally, the size or type of a particular wound may prevent the use of sutures to promote wound closure. It therefore becomes desirable to provide an apparatus and method for closing a large wound that distributes a closure force evenly about the periphery of the wound.

Wounds resulting from ischemia, or lack of blood flow, are also often difficult to heal since decreased blood flow to a wound may inhibit normal immune reaction to fight infection. Patients that are bedridden or otherwise non-ambulatory are susceptible to such ischemic wounds as decubitus ulcers or pressure sores. Decubitus ulcers form as a result of constant

compression of the skin surface and underlying tissue thus restricting circulation. Since the patient is often unable to feel the wound or to move sufficiently to relieve the pressure, such wounds can become self-perpetuating. Although it is common to treat such wounds with flaps, the conditions that initially caused the wound may also work against successful flap attachment. Wheelchair-bound paraplegics, for example, must still remain seated after treatment of pelvic pressure sores. It therefore becomes desirable to provide a treatment procedure for ischemic wounds that can be conducted in situ upon an immobile or partially mobile patient.

Other types of wounds in which ischemia leads to progressive deterioration include partial thickness burns. A partial thickness burn is a burn in which the cell death due to thermal trauma does not extend below the deepest epidermal structures such as hair follicles, sweat glands, or sebaceous glands. The progression of partial thickness burns to deeper burns is a major problem in burn therapy. The ability to control or diminish the depth of burns greatly enhances the prognosis for burn patients and decreases morbidity resulting from burns. Partial thickness burns are formed of a zone of coagulation, which encompasses tissue killed by thermal injury, and a zone of stasis. The zone of stasis is a layer of tissue immediately beneath the zone of coagulation. Cells within the zone of stasis are viable, but the blood flow is static because of collapse of vascular structures due to localized edema. Unless blood flow is re-established within the zone of stasis soon after injury, the tissue within the zone of stasis also dies. The death of tissue within the zone of stasis is caused by lack of oxygen and nutrients, reperfusion injury (re-establishment of blood flow after prolonged ischemia), and decreased migration of white blood cells to the zone resulting in bacterial proliferation. Again, it becomes desirable to provide a technique for treating burn wounds by enhancing blood circulation to the wounded tissue to inhibit burn penetration.

There exist various apparatus utilizing reduced pressure for treatment of these types of wounds. See, for example, U.S. Patent No. 5,636,643. The apparatus existing in the art is generally comprised of a fluid impermeable cover that covers the wound, which is directly or indirectly connected to a source of suction so that an area of reduced pressure is created beneath the cover in the area of the wound. Some type of packing material, such as gauze, is also often placed in the area of the wound beneath the cover to prevent overgrowth of the wound. Apparatus existing in the relevant art, however, suffer from several disadvantages.

One such disadvantage is the necessity to change the packing material placed in the wound during the period of treatment. This requirement is expensive because multiple dressings are necessary and medical staff must expend time to change the dressings. In addition, there is an increased risk of infection and intrusion of other harmful foreign material into the wound area. It is therefore desirable to have a reduced pressure wound treatment system having a dressing that does not need to be changed, or needs to be changed fewer times, during the period of treatment.

In addition, the existing apparatus do not have adequate means to monitor the pressure in the area of the wound beneath the cover. If the cover is not adequately sealed to the tissue surrounding the wound, reduced pressure cannot be maintained beneath the cover so that the benefits of the treatment are lost or diminished. In addition, pressure leaks through the seal cause the source of suction to operate more frequently, which consumes more energy and causes the suction equipment to wear faster than it would otherwise, reducing its useful life. Further, the flow of air into the wound area as a result of such leaks can result in increased risk of infection and intrusion of other harmful foreign material into the wound area. It is therefore desirable to have a relatively inexpensive means of monitoring the pressure level beneath the

cover at the site of the wound.

In addition, the existing apparatus do not have a means to determine the amount of blood flow to the tissue at the site of the wound. As discussed above, adequate blood circulation in the area of the wound is essential for the healing process to proceed as desired. Areas of tissue having an increased level of blood circulation generally have a higher temperature than areas that have a comparatively lower level of blood circulation. It is therefore desirable to have a means of monitoring the relative temperature within the area of the wound.

Finally, it is sometimes necessary to transport patients in need of reduced pressure wound care. It is also sometimes necessary to provide reduced pressure treatment in the field. It is therefore also desirable to have a wound treatment apparatus that is portable and self-contained, which can accompany the patient during such transport or be used to provide reduced pressure treatment in the field.

SUMMARY

The present invention is directed to a reduced pressure wound treatment apparatus and method that satisfy the needs described above. As described in greater detail below, it has many advantages over existing apparatus when used for its intended purpose, as well as novel features that result in a new reduced pressure wound treatment apparatus and method that are not anticipated, rendered obvious, suggested, or even implied by any of the prior art helmets, either alone or in any combination thereof.

In accordance with the present invention a wound treatment apparatus is provided for treating a wound by applying reduced pressure (i.e. pressure that is below ambient atmospheric

pressure) to the wound in a controlled manner for a selected time period in a manner that overcomes the disadvantages of currently existing apparatus. The application of reduced pressure to a wound provides such benefits as faster healing, increased formation of granulation tissue, closure of chronic open wounds, reduction of bacterial density within wounds, inhibition of burn penetration, and enhancement of flap and graft attachment. Wounds that have exhibited positive response to treatment by the application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached.

The wound treatment apparatus in accordance with the present invention includes a reduced pressure application appliance that is applied to a treatment site at which there is a wound and normal tissue surrounding the wound. The reduced pressure application appliance includes a fluid impermeable wound cover for covering and enclosing the wound. In a particular embodiment of the present invention, the wound cover also includes means for visually monitoring the pressure in the area of the site of the wound beneath the wound cover. These means include a plurality of protrusions on the surface of the cover that are recessed when a predetermined pressure is present beneath the cover, but are increasingly displaced above the remaining surface of the cover as the pressure beneath the cover increases above a predetermined pressure. In a similar manner, the cover may contain areas that are displaced as protrusions away from the remaining surface of the cover toward the wound when reduced pressure is applied beneath the cover, and the displacement of the protrusions decreases as the pressure beneath the cover increases. The protrusions may also be a different color (or a different shade of the same color) from that on the remaining surface of the cover. In addition, the protrusions may produce a noise as they are displaced away from the remaining surface of the cover, providing an audible indication that the pressure beneath the cover is increasing.

The appliance also includes sealing means for sealing the wound cover to the surrounding tissue of the wound in order to maintain reduced pressure in the vicinity of the wound during wound treatment. When the wound cover is sealed in position over the wound site, a generally fluid-tight or gas-tight sealed enclosure is formed over the wound site. The sealing means may be in the form of an adhesive applied to the underside of the wound cover for sealing the wound cover around the periphery of the wound. The sealing means may also include a separate sealing member such as an adhesive strip or a sealing ring in the form of a tubular pad or inflatable cuff secured to the wound cover for positioning around the periphery of the wound. In selected embodiments, the reduced pressure within the sealed enclosure under the wound cover may serve to seal the wound cover in position at the wound site. The reduced pressure appliance also includes a suction port for supplying reduced pressure within the sealed volume enclosed beneath the wound cover. The suction port may be in the form of a nipple on the wound cover. Alternatively, the suction port may be in the form of a tube attached to the wound cover or provided as a feedthrough beneath the wound cover.

The appliance may also include an absorbable matrix for placement in the wound in order to encourage tissue in the area of the wound to grow into the matrix during treatment. The absorbable matrix is constructed of an absorbable material that is absorbed into the epithelial and subcutaneous tissue in the wound as the wound heals. The matrix may vary in thickness and rigidity, and it may be desirable to use a spongy absorbable material for the patient's comfort if the patient must lie upon the appliance during treatment. The matrix may also be perforated and constructed in a sponge-type or foam-type structure to enhance gas flow and to reduce the weight of the matrix. Because of the absorbable nature of the absorbable matrix, the matrix should require less frequent changing than other dressing types during the treatment process. In

other circumstances, the matrix may not need to be changed at all during the treatment process.

A vacuum system is connected with the reduced pressure appliance in order to provide suction or reduced pressure to the appliance. For this purpose, the vacuum system includes a suction pump or suction device for connection with the suction port of the appliance for producing the reduced pressure over the wound site. The vacuum system may include a section of hose or tube, such as a vacuum hose, that interconnects the suction device with the suction port of the appliance to provide the reduced pressure at the wound site. A fluid collection system may be provided intermediate the vacuum hose of the suction device and the suction port of the appliance to trap any exudate that may be aspirated from the wound by the negative pressure appliance. A stop mechanism may also be provided for the vacuum system to halt production of the reduced pressure at the wound site in the event that an excessive quantity of exudate has been collected. The apparatus may also include a control device for controlling the pump.

In a particular embodiment of the invention, the wound cover for the reduced pressure appliance may be in the form of a gas impermeable covering sheet of flexible polymer material, such as polyethylene, having an adhesive backing that provides the seal for securing the sheet over the wound site to provide an gas-tight or fluid-tight sealed enclosure over the wound site. The vacuum system of the wound treatment apparatus may include a suction pump having a vacuum hose that is connected with a suction tube serving as a suction port for the appliance. The suction tube for the appliance runs beneath the cover sheet that is sealed in position over the wound site and into the fluid-tight enclosure provided under the cover sheet. An adhesive backing on the cover sheet is used to provide a fluid-tight seal around the feedthrough for the suction tube at the wound site. Within the enclosure, the suction tube is connected with the absorbable matrix for placement in the wound. The absorbable matrix functions to more

uniformly apply reduced pressure or suction over the wound site while holding the cover sheet substantially out of the wound during the application of reduced pressure at the enclosed wound site.

In another particular version of the invention, the wound treatment apparatus also includes means to monitor the temperature of the tissue in the area of the wound. In a particular embodiment of this version of the invention, a temperature sensitive layer composed of a temperature sensitive material is placed adjacent to the lower surface of the wound cover. The temperature sensitive layer changes color, or changes from one shade of a color to another shade of the same color, as the temperature of the material changes. In this embodiment of the invention, the wound cover is composed of a transparent or semi-transparent material allowing the temperature sensitive material to be observed from above the wound cover. Alternatively, the wound cover is composed of a temperature sensitive material that changes color, or changes from one shade of a color to another shade of the same color, as the temperature of the material changes. In another embodiment of this version of the invention, one or more temperature measuring devices are placed in the area of the wound. The temperature measuring devices are preferably placed adjacent to the wound tissue, but may also be placed in other locations under or above the wound cover, to monitor the temperature of said tissue. Temperature measuring devices located under the wound cover have leads that feedthrough beneath the wound cover. The leads are connected to an alarm system that produces one or more alarm signals when the temperature measured by one or more of the temperature measuring devices exceeds or is lower than a predetermined value. In another embodiment of this version of the invention, the temperature measuring devices are also connected through their respective leads and the alarm system to a temperature display or recording device that produces a display or record of the temperature in the area of the wound.

In another particular version of the invention, the wound treatment apparatus is portable and self-contained. In this version of the invention, a miniature vacuum source is used to provide suction to the reduced pressure appliance. Similarly, the fluid collection system is of the minimum size desired to collect and maintain the amount of exudate expected to be aspirated from the wound during the time of anticipated use of the portable wound treatment apparatus. A filter may also be placed in the connection between the vacuum source and the fluid collection system to avoid contamination of the source by the fluid aspirated from the wound. As a result, reduced pressure treatment of a wound can continue even if it becomes necessary to transport the patient because the apparatus can accompany a patient during the transport. The portable apparatus is not, however, limited to this use alone. It can be used in any application where a portable treatment apparatus is advantageous, such as treatment of wounds in the field.

There has thus been outlined, rather broadly, the more primary features of the present invention. There are additional features that are also included in the various embodiments of the invention that are described hereinafter and that form the subject matter of the claims appended hereto. In this respect, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the following drawings. This invention may be embodied in the form illustrated in the accompanying drawings, but the drawings are illustrative only and changes may be made in the specific construction illustrated and described within the scope of the appended claims. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of the description and should not be regarded as limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description of the preferred embodiments of the present invention, will be better understood when read in conjunction with the appended drawings, in which:

FIG. 1 is a schematic elevational view of a wound treatment apparatus in accordance with a particular embodiment of the present invention in which a reduced pressure appliance, shown in partial section, includes a flexible, fluid impermeable wound cover sealed over the wound and an absorbable matrix positioned in the wound, and in which a vacuum system provides reduced pressure within the wound cover of the appliance;

FIG. 2a is a schematic sectional elevational view of the reduced pressure appliance of FIG. 1, illustrating an absorbable matrix having three layers of absorbable material, such layers being of different absorbable materials;

FIG. 2b is a schematic sectional elevational view of the reduced pressure appliance of **FIG. 1**, illustrating an absorbable matrix having generally concentric layers of absorbable material, such layers being of different absorbable materials;

FIG. 3 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention, shown in partial section, in which the reduced pressure appliance includes a rigid, fluid impermeable, cone-shaped wound cover overlying the wound site;

FIG. 4a is a schematic elevational view of a wound treatment apparatus in accordance with a particular embodiment of the present invention in which a reduced pressure appliance, shown in partial section, includes a flexible, fluid impermeable wound cover sealed over the wound and an absorbable matrix positioned in the wound, and in which a vacuum system provides reduced pressure within the wound cover of the appliance;

FIG. 4b is a sectional elevational detailed view of the shutoff mechanism portion of the collection system of **FIG. 4a**;

FIG. 5a is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention, shown in partial section, in which the reduced pressure appliance includes a flexible, fluid impermeable wound cover sealed over the wound, said cover having embedded within it protrusions that are displaced above the remaining surface of the cover;

FIG. 5b is a detailed perspective view of a protrusion from the reduced pressure appliance of **FIG. 5a**, in the fully displaced configuration;

FIG. 5c is a schematic sectional elevational view of the reduced pressure appliance of **FIG. 5a**, illustrating the cover having the protrusions in the depressed configuration when sufficient vacuum is present beneath the cover;

FIG. 5d is a detailed perspective view of a protrusion from the reduced pressure appliance of **FIG. 5a**, in the fully depressed configuration;

FIG. 5e is a schematic sectional elevational view of the reduced pressure appliance of **FIG. 5a**, illustrating alternative protrusions having a bellows-type of configuration;

FIG. 5f is a perspective view of the reduced pressure appliance of **FIG. 5a**, illustrating a pattern of protrusions on the wound cover;

FIG. 6 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention, shown in partial section, in which the reduced pressure appliance includes a packing material or an absorbable matrix positioned in the wound, and a flexible, fluid impermeable wound cover sealed over the wound, and a layer of temperature sensitive material located between the cover and the wound;

FIG. 7 is a schematic sectional elevational view of a reduced pressure appliance in accordance with another embodiment of the present invention, shown in partial section, in which the reduced pressure appliance includes a packing material positioned in the wound, and a flexible, fluid impermeable wound cover sealed over the wound, and a plurality of temperature sensors located at and surrounding the site of the wound, and in which an alarm system and a temperature display and recording device are connected to the temperature sensors;

FIG. 8a is a perspective view of a wound treatment apparatus in accordance with another embodiment of the present invention, shown from above, in which a reduced pressure appliance, a vacuum source, a filter, and a fluid collection system are connected together as a compact and portable apparatus; and

FIG. 8b is a sectional elevational detailed view of the shutoff mechanism portion of the

collection system of **FIG. 8a**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with the present invention, a wound treatment apparatus is provided for treating a wound by application of reduced pressure (i.e., below atmospheric pressure) so that suction may be applied to a wound site **25** in a controlled manner for a selected period of time. **FIG. 1** schematically shows one version of the wound treatment apparatus, generally designated **20**, which includes a reduced pressure appliance, generally designated **30**, for enclosing a wound site **25** to provide a fluid-tight or gas-tight enclosure over the wound site **25** to effect treatment of a wound **25** with reduced or negative pressure. For the purpose of creating suction within the appliance **30**, the appliance **30** is connected with a vacuum system, generally designated **50**, to provide a source of suction or reduced pressure for the sealed appliance **30** at the wound site **25**. Intermediate the appliance **30** and the vacuum system **50** is a fluid collection system, generally designated **70**, for intercepting and retaining exudate that is aspirated from the wound site **25**.

FIG.1 also illustrates one embodiment of the reduced pressure appliance **30**, which includes an absorbable matrix **32** that is placed within the wound **25**, a fluid impermeable wound cover **40**, and a suction port in the form of hollow tubing **45** that connects the appliance **30** to the vacuum system **50** (through the collection system **70**) to provide reduced pressure in the area beneath the cover **40** in the area of the wound **25**. **FIG. 1** also illustrates one embodiment of an absorbable matrix **32**, which is placed within the wound **25**.

The absorbable matrix **32** is placed over substantially the expanse of the wound **25** to encourage growth of tissue in the area of the wound **25** into the matrix **32** as the wound heals.

The size and configuration of the absorbable matrix **32** can be adjusted to fit the individual wound **25**. It can be formed from a variety of absorbable materials, preferably a material that is also porous. The matrix **32** should be constructed in a manner so that it is sufficiently porous to allow oxygen to reach the wound **25**. The absorbable matrix **32** is preferably constructed of a non-toxic material that is absorbable by the epithelial and subcutaneous tissue within the area of the wound **25**, such as collogens derived from healthy mammals, absorbable synthetic polymers, or other materials similar to those used for absorbable dressings. An example is a dehydrating material derived from seaweed for treatment of exudating wounds. The matrix **32** may vary in thickness and rigidity, although it may be desirable to use a spongy or layered, non-woven absorbable material for the patient's comfort if the patient must lie upon the appliance **30** during treatment. The matrix **32** may also be perforated and constructed in a foam-type, sponge-type, or non-woven layered structure to enhance gas flow and to reduce the weight of the appliance **30**. As shown in **FIG. 1**, the matrix **32** is cut to an appropriate shape and size to fit within the wound **25**. Alternatively, the matrix **32** may be sufficiently large to overlap the surrounding skin **24**. Further, the matrix **32** may be of uniform thickness over its entire area, as is the case where monitoring the temperature of tissue in the area of the wound is desired as a part of the treatment process.

In another embodiment of the invention, the absorbable matrix **32** has the same features as described above and as illustrated in **FIG. 1**, but may also be constructed of more than one absorbable material, such material having different rates of absorption into body tissue. By preselecting the materials of the matrix **32**, and placing them in areas of the wound **25** in which different rates of absorption are desired, it may be possible to enhance wound healing. An example of this embodiment of the absorbable matrix **32** is illustrated in **FIG. 2a**, where the matrix **32** is composed of three layers, each layer being composed of an absorbable material

different from the material in the adjacent layer. Thus, in a matrix **32** of three layers having the lowest layer **33** being constructed of an absorbable material, and the middle layer **34** of the matrix **32** being constructed of a material having a lower rate of absorption than the lowest layer **33**, and the layer of the matrix **32** closest to the cover **40** (i.e., the highest layer **35**) being constructed of a material having a rate of absorption lower than the other two layers, the area of the wound **25** adjacent to the lowest layer **26** would be allowed to close at a faster rate than the area of the wound **25** adjacent to the middle layer **27**, and the area of the wound **25** adjacent to the highest layer **28** would be allowed to close at a faster rate than the area of the wound **25** adjacent to the middle layer **27** and the lowest layer **26**. This embodiment of the invention is not limited to three layers or this gradation of absorption rates. Any combination of number of layers and absorbent materials desirable for wound treatment is possible and may be preferred. For example, the matrix **32** may have a highest layer **35** of absorbent material having a rate of absorption higher than the rate of absorption of the middle layer **34**, which middle layer **34** has a higher rate of absorption than the rate of absorption of the lowest layer **33**. Similarly, the highest layer **35** and the lowest layer **33** may have rates of absorption that are approximately equal to one another, such rate of absorption being greater or lesser than the rate of absorption of the middle layer **33**.

In addition, this embodiment of the matrix **32** is not limited to layers. The matrix **32** may be constructed in any configuration having materials of different absorption rates in any portion of the matrix **32** that is desired to promote wound healing. For example, as illustrated in **FIG. 2b**, the material on the periphery **36** of the matrix **32** may be constructed of material having one rate of absorption, while the inner portions **37** of the matrix **32** may be constructed of one of more materials having different rates of absorption. This would allow for the wound **25** to close at one rate during the initial portion of the treatment period, and for the wound **25** to close at

different rates during later portions of the treatment period. Other configurations that are possible include having approximately opposite sides or ends of the matrix **32** being constructed of a different material from the intermediate portions of the matrix **32**.

The fluid-impermeable wound cover **40** in the embodiment of the reduced pressure appliance **30** illustrated in **FIG. 1** is in the form of a flexible, adhesive, fluid impermeable polymer sheet for covering and enclosing the wound **25**, including the absorbable matrix **32** within it, and the surrounding normal skin **24** at the wound site **25**. The wound cover **40** includes an adhesive backing **41** which functions to seal the wound cover **40** to the normal skin **24** around the periphery of the wound **25** to provide a generally gas-tight or fluid-tight enclosure over the wound **25**. The adhesive cover sheet **40** must have sufficient adhesion to form a fluid-tight or gas-tight seal **42** around the periphery of the wound **25** and to hold the sheet **40** in sealed contact with the skin **24** during the application of suction or reduced or negative pressure. The wound cover **40** also provides a gas-tight seal around the tubing **45** at the feedthrough location **46** where the tubing **45** emerges from beneath the wound cover **40**. The wound cover **40** is preferably formed of a fluid impermeable or gas impermeable flexible adhesive sheet such as Ioban, a product of the 3M Corporation of Minneapolis, Minnesota.

The reduced pressure appliance **30** is not, however, limited to the configuration illustrated in **FIG. 1**. The appliance **30** may also have a wound cover of almost any size, shape, and configuration adapted to treat the wound. An example of this type of cover **40** is illustrated in the embodiment of the appliance **30** shown in **FIG. 3**, which has a wound cover **140** comprised of a rigid, fluid impermeable, generally cone-shaped wound cover **140** overlying the wound site **25**. Alternatively, the cover overlying the wound site may be comprised of a rigid, fluid impermeable, flat, bowl-shaped, or cup-shaped wound cover to protect the site of a wound

25 from impact or abrasion during treatment. The wound cover may also be comprised of a fluid impermeable, flexible cover supported by rigid support members overlying the wound site **25**. All of these cover types may be sealed to the normal skin **24** surrounding the wound **25** by using the suction created under the cover and a soft and flexible padding material **143** around the periphery of the cover **140**, which is in contact with the skin **24**. More preferably, the cover **140** is sealed to the skin **24** using a fluid-impermeable adhesive material **141** such as an adhesive tape or an adhesive sheet that has been cut to surround and at least partially overlie the periphery of the cover **140**. As an additional example, the cover may be comprised of a CPR mask, which may be sealed to the skin surrounding the wound with an inflatable air cuff that is a part of the mask, with a fluid-impermeable adhesive material, or by some other fluid-impermeable means. Where the cover **140** is not in contact with the absorbable matrix **32**, and is therefore not exerting force adequate to keep the matrix **32** in place within the wound **25**, a rigid or semi-rigid porous screen **147** may be placed over the matrix **32** and under the cover **140** in a position so that the periphery of such screen **147** is held in place by a portion of the cover **140** or the seal **142** that holds the cover **140** in place against the skin **24**. In such case, the screen **147** is of a thickness and rigidity necessary to hold the matrix **32** in place within the wound **25**, but having a porous structure so that fluids (including gases) are able to pass through the screen **147**.

The appliance **30** also includes a suction port in the form of a hollow suction tube **45** that connects with the vacuum system **50** to provide suction within the sealed enclosure. The suction tubing **45** serves as a suction port for the appliance **30**. In the embodiment of the invention illustrated in **FIG. 1**, an end segment **45a** of the tubing **45** is embedded within the absorbable matrix **32** for providing suction or reduced pressure within the enclosure provided under the wound cover **40**. Embedding the open end of segment **45a** of tubing **45** within the interior of the absorbable matrix **32** permits the absorbable matrix **32** to function as a shield to help prevent the

wound cover **40** from being inadvertently sucked into sealing engagement with the open end of the tube thereby plugging the tube **45** and restricting gas flow. The tube segment **45a** embedded within the absorbable matrix **32** preferably has at least one side port **47** for positioning within the interior of the absorbable matrix **32** to promote substantially uniform application of reduced pressure throughout the enclosure. Positioning the side port **47** of tube segment **45a** within the interior of the absorbable matrix **32** permits the absorbable matrix **32** to function as a shield for the side port to thereby prevent the wound cover **40** from being sucked into the side port **47** and thereby restricting gas flow. The open cells of the absorbable matrix **32** facilitate gas flow throughout the enclosure. In addition, the absorbable matrix **32** functions to encourage the growth of tissue in the area of the wound **25** into the matrix **32** and to hold the wound cover **40** generally out of contact with the wound **25** during the application of suction within the enclosure.

Tubing **45** and tube segment **45a** are sufficiently flexible to permit movement of the tubing but are sufficiently rigid to resist constriction when reduced pressure is supplied to the appliance **30** or when the location of the wound **25** is such that the patient must sit or lie upon the tubing **45** or upon the reduced pressure appliance **30**. The matrix-tube assembly comprising the absorbable matrix **32** and the tube **45** may be fabricated by snaking the end of the tube segment **45a** through an internal passageway in the absorbable matrix **32** such as by pulling the end of the tube segment **45a** through the passageway using forceps. The matrix-tube assembly **32** and **45** is preferably prepared prior to use under sterile conditions and then stored in an aseptic package.

As shown in **FIG. 4a**, the vacuum system **50**, which produces a source of reduced pressure or suction that is supplied to the reduced pressure appliance **30**, includes a vacuum

pump **51**, a control device **52**, a filter **53**, and tubing **54** that connects the vacuum pump **51** to the collection system **70**. Predetermined amounts of suction or reduced pressure are produced by the vacuum pump **51**. The vacuum pump **51** is preferably controlled by a control device **52** such as a switch or a timer that may be set to provide cyclic on/off operation of the vacuum pump **51** according to user-selected intervals. Alternatively, the vacuum pump **51** may be operated continuously without the use of a cyclical timer. A filter **53** such as micropore filter is preferably attached to the exhaust of the pump **51** to prevent potentially pathogenic microbes or aerosols from being vented to atmosphere by the vacuum pump **51**.

As shown in **FIG. 4a**, a fluid collection system, generally designated **70**, is interconnected between the suction pump **51** and the appliance **30** to remove and collect any exudate which may be aspirated from the wound **25** by the reduced pressure appliance **30**. The appliance **30** functions to actively draw fluid or exudate from the wound **25**. Collection of exudate in a fluid collection system **70** intermediate the pump **51** and the appliance **30** is desirable to prevent clogging of the pump **51**. The fluid collection system **70** is comprised of a fluid-impermeable collection container **71** and a shutoff mechanism **75**. The container **71** may be of any size and shape capable of intercepting and retaining a predetermined amount of exudate. Many examples of such containers are available in the relevant art. The preferred container in this embodiment of the invention is illustrated in side elevation view in **FIG. 4a**, said container having two openings in the top of the container **71**. The container **71** includes a first port **72** at the top opening of the container for sealed connection to suction tubing **45**. The first port **72** enables suction to be applied to the reduced pressure appliance **30** through the tubing **45** and also enables exudate from the wound **25** covered by reduced pressure appliance **30** to be drained into the container **71**. The container **71** provides a means for containing and temporarily storing the collected exudate. A second port **73** is also provided on the top of the

container to enable the application of suction from the vacuum pump **51**. The second port **73** of the collection system **70** is connected to the vacuum pump **51** by a vacuum line **54**. The collection system **70** is sealed generally gas-tight to enable the suction pump **51** to supply suction to the appliance **30** through the collection system **70**.

The container **71** may also include a fluid impenetrable flexible liner within its volume that is used to collect the exudate in a manner that avoids contaminating the container **71** with pathogenic microbes and other harmful matter present in the exudate. In such case, the flexible liner may be directly connected to the first port **72** and second port **73** in a manner so that no exudate comes into direct contact with the container **71**. In this embodiment, the preferred liner is a flexible bag constructed of a polymer material, which is connected to the first port **72**.

The vacuum system **50** and collection system **70** preferably include a shutoff mechanism for halting or inhibiting the supply of the reduced pressure to the appliance **30** in the event that the exudate aspirated from the wound **25** exceeds a predetermined quantity. Interrupting the application of suction to the appliance **30** is desirable to prevent exsanguination in the unlikely event a blood vessel ruptures under the wound cover **40** during treatment. If, for example, a blood vessel ruptures in the vicinity of the wound **25**, a shut-off mechanism would be useful to prevent the vacuum system **50** from aspirating any significant quantity of blood from the patient.

The shutoff mechanism **75** may be comprised of any means that enables the vacuum system **50** to halt the supply of reduced pressure to the wound cover **40** at any time that the volume of exudate from the wound **25** exceeds a predetermined amount. Such means may include mechanical switches, electrical switches operably connected to the vacuum system controller **52**, optical, thermal or weight sensors operably connected to the vacuum system

controller **52**, and any other means that are currently known in the relevant art or which may hereafter be discovered. The shutoff mechanism **75**, as illustrated in **FIG. 4b**, is preferably a float valve assembly in the form of a ball **76** which is held and suspended within a cage **77** positioned below a valve seat **78** disposed within the opening at the top of the container below the second port that will float upon the exudate and will be lifted against the valve seat **78** as the container fills with exudate. When the ball **76** is firmly seated against the valve seat **78**, the float valve blocks the second port **73** and thereby shuts off the source of suction from the vacuum system **50**. Other types of mechanisms may also be employed to detect the liquid level within the container **71** in order to arrest operation of the vacuum system **50**.

In another version of the invention, the wound treatment apparatus includes means to monitor the pressure beneath the wound cover **40** at the site of the wound **25**. In one embodiment of this version of the invention, as illustrated in **FIG. 5a**, the wound cover **40** has a plurality of protrusions **60** in the form of "hills" or "bumps" embedded in the cover **40**. As illustrated in **FIG. 5a**, the protrusions **60** protrude above the remaining surface **43** of the cover **40** when the cover **40** is not in use for wound treatment. A detailed view of a protrusion **60a** in this configuration is shown in perspective view in **FIG. 5b**. Generally, as illustrated in **FIG. 5c**, when the cover **40** is in use (i.e., sealed over the wound site **25** with reduced pressure applied beneath the cover **40**), the protrusions **60** are displaced downward so that they are depressed to a level almost the same as that of the remaining surface **43** of the cover **40**. A detailed view of a protrusion **60b** in the depressed configuration is shown in perspective view in **FIG. 5d**. In another embodiment, the protrusions **60c** are configured in the form of bellows, as shown in **FIG. 5e**. In this version of the invention, as the pressure beneath the cover **40** decreases (i.e., the level of reduced pressure increases), the top of the protrusion **60c** is displaced downward toward the level of the remaining surface **43** of the cover **40**. The protrusions **60** may be placed in any

location, as well as in any pattern or lack of pattern, on the surface of the cover **40**. An example of one possible pattern is illustrated in **FIG. 5f**.

The protrusions **60** may be constructed of the same material as the remainder of the cover **40**, or may be constructed of a material different from the remainder of the cover **40**, depending upon the sensitivity of pressure monitoring desired. Similarly, the protrusions **60** may be constructed of material having the same thickness as the remainder of the cover **40**, or material of a different thickness, depending upon the sensitivity of pressure monitoring desired. For example, if the reduced pressure beneath the cover **40** is of a relatively low level, so that the difference between the ambient atmospheric pressure above the cover **40** is relatively small when compared to the reduced pressure beneath the cover **40**, it may be desirable to have the protrusions **60** be able to change shape with relatively small changes in pressure beneath the cover **40** during the treatment period. In such case, it may be preferable to have the protrusions **60** of a thickness less than the thickness of the remaining cover material. It may also be preferable to have the protrusions **60** constructed of a material more pliable than the material of which the remainder of the cover **40** is constructed. Similarly, if the reduced pressure beneath the cover **40** is of a relatively high level, so that the difference between the ambient atmospheric pressure above the cover **40** is relatively large when compared to the reduced pressure beneath the cover **40**, it may be desirable to have the protrusions **60** be able to change shape with relatively large changes in pressure beneath the cover **40** during the treatment period. In such case, it may be preferable to have the protrusions **60** of a thickness more similar to the thickness of the remaining cover material. It may also be preferable to have the protrusions **60** constructed of a material that is more similar to the material of which the remainder of the cover **40** is constructed in terms of pliability.

By preselecting the thickness and pliability of the material used to construct the protrusions **60**, it may also be possible to monitor the pressure by partial deflections of the protrusions **60**. For example, the protrusions **60** may be displaced in an increasing amount above the remaining surface **43** of the cover **40** as the pressure beneath the cover **40** increases (i.e., the level of reduced pressure decreases). This relationship of displacement of the protrusions **60** to the increase in pressure beneath the cover **40** may be linear or based upon some other function. Similarly, the protrusions **60** may be constructed so that they only begin to be displaced when a predetermined pressure differential occurs between the area under the cover **40** and the area above the cover **40**. It should be noted, however, that this version of the invention is intended as a means to provide an inexpensive and approximate visual indication of the occurrence of loss of reduced pressure beneath the cover and may not be a means to accurately measure the actual pressure beneath the cover or the actual difference between the pressure above the cover and the reduced pressure beneath the cover.

As a result, the preferable thicknesses and materials to be used in constructing the cover **40** and protrusions **60** in this version of the invention are dependent upon a multitude of factors, including the desired pressure beneath the cover **40**. Preferably, the wound cover **40** is constructed of polyurethane, having a thickness of only a few mils to 1/8th inch, and having protrusions **60** constructed of the same material as the remaining portion of the cover **40**, said protrusions **60** having a thickness only slightly less than the thickness of the cover **40** to a relatively small fraction of the thickness of the cover **40**.

Further, the protrusions **60** may be constructed of material that is of a different color than the color of the remaining surface **43** of the cover **40**. Similarly, the protrusions **60** may be of a different shade of the same color as the remaining surface **43** of the cover **40**. As the protrusions

60 are displaced away from the remaining surface **43** of the cover **40**, the protrusions **60** may change color as a result of the expansion of the material comprising the protrusions 60.

In another embodiment of this version of the invention, the protrusions work in the manner opposite to that described above. In this embodiment, the cover has within it a plurality of areas that are displaced away (i.e., pulled down) from the remaining surface of the cover toward the wound when reduced pressure is applied beneath the cover. This downward displacement is the result of the reduced pressure suction, which causes tension that pulls the protrusions away from the remaining surface of the cover. As the pressure beneath the cover increases, the tension on the protrusions weakens allowing the protrusions to recede back into the cover. The principles discussed above with respect to thickness, materials, color, and partial deflection monitoring of pressure apply to this embodiment of the invention as well. It should be noted that bellows-type protrusions are not used in this embodiment.

The protrusions **60** may also have a means whereby they produce an audible sound as the protrusions **60** are being displaced away from the remaining surface **43** of the cover **40**. This sound may be produced by the "crinkling" or vibration of the material as it is displaced away from the remaining surface **43** of the cover **40**.

It should be noted that the means to monitor the pressure beneath the cover described in this embodiment of the invention may be used independently of any other feature of this invention. In addition, the means to monitor pressure beneath the cover is not limited to use in treatment of open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached. Instead, said pressure monitoring means may be used in any application involving reduced pressure in the treatment of any portion

of the body of a patient, such as cosmetic surgery, cosmetic healing, and prophylactic suctioning for cosmetic and psychological reasons. In addition, the cover may be of any configuration, including the cover configurations specifically discussed above. Further, it is not necessary that any packing material or matrix be present in the area of the wound beneath the cover in this version of the invention. Nor is it necessary that the features included in this version of the invention be included as a part of any other version or embodiment of this invention.

In another version of the invention, the wound treatment apparatus includes means to monitor the temperature in the area of the wound **25**. In one embodiment of this second version of the invention, as illustrated in **FIG. 6**, a layer of temperature sensitive material **80** is placed adjacent to the lower surface **44** of the wound cover **40**. Alternatively, the cover **40** and the layer **80** may be joined together to form a single integrated unit. In such case, the cover **40** and the layer **80** may be joined in any manner that is fluid-impermeable and allows the color (or other property exhibiting the change of temperature) of the temperature sensitive layer **80** to be observed from above the wound cover **40**. The preferred means to join the cover **40** and the layer **80** is a transparent or semi-transparent adhesive material. Alternatively, the wound cover **40** may itself be composed of a temperature sensitive material, so that a separate temperature sensitive layer is not required.

The temperature sensitive layer **80** (or the cover **40**, if it is composed of a temperature sensitive material) may be composed of any material that changes properties in a manner that does not adversely affect the operation of the reduced pressure appliance **30**. Preferably, the temperature sensitive layer **80** is composed of a material that changes color, or changes from one shade of a color to another shade of the same color, as the temperature of the material changes. The change in color or shade preferably occurs within the temperature range that may be

expected in the area of the wound **25**. In other words, the change in color or shade of the material should be significant enough to adequately indicate changes in temperature within the range of temperatures expected in the area of the wound **25**. More preferably, the temperature sensitive material is a material that changes temperature in the range from approximately 95 degrees Farenheit to approximately 105 degrees Farenheit.

In the embodiment of the invention shown in **FIG. 6**, the temperature sensitive layer **80** is placed over a packing material or matrix **32a**, which packing material or matrix **32a** is placed within the area of the wound **25**. The matrix **32a** may be an absorbable matrix **32a**, as described above. The packing material may be constructed of any material that is suitable for placement within a wound **25**, which may be to prevent its overgrowth, but still allows for fluid and gas flow to and from the wound **25**, such as a porous polymer material or gauze. In order to provide for uniform temperature monitoring, the packing material or matrix **32a** is preferably of relatively uniform thickness when placed within the area of the wound **25**. In addition, the packing material or matrix **32a** should be thin enough to allow for the temperature of the tissue to affect the temperature of the temperature sensitive layer **80**. More preferably, the thickness of the packing material or matrix **32a** should not exceed slightly greater than zero to one half inches. The packing material or matrix **32a** may, however, be of non-uniform thickness where the temperature sensitive layer **80** is comprised of temperature sensitive material in a manner that compensates for the differences in thickness of the packing material or matrix **32a**.

The wound cover **40** is placed over the temperature sensitive layer **80** and sealed to the normal skin **24** surrounding the wound **25**. If the cover **40** and the temperature sensitive layer **80** are an integrated unit, however, the unit is placed over the packing material or matrix **32a** without a separate temperature sensitive layer **80**. If the cover **40** is composed of a temperature

sensitive material, it is placed over the packing material or matrix without an additional temperature sensitive layer **80**. It should be noted, however, that the temperature sensitive material used in this embodiment of the invention is intended as a means to provide an approximate visual indication of the temperature in the area of the wound **25** beneath the cover **4**, and may not accurately measure the actual temperature beneath the cover **40**.

In another embodiment of this second version of the invention, one or more temperature measuring devices **81** are placed within the area of the wound **25** and connected to an alarm system, generally designated as **82**. The temperature measuring devices **81** may also be connected to a temperature display and recording device **83**. An example of this embodiment is illustrated in **FIG. 7**, which shows temperature measuring devices **81** placed in the area of the wound **25**. The temperature measuring devices **81** may be placed in any area of the wound **25** and the reduced pressure appliance **30**. For example, the temperature measuring devices **81** may be placed adjacent to and in direct contact with the tissue in the area of the wound **25**. Alternatively, the temperature measuring devices **81** may be embedded in any packing material or matrix **32** placed in the area of the wound **25**, or in the area between such packing material or matrix **32** and the cover **40**, or embedded within the cover **40**, or adjacent to either surface of the cover **40**.

The temperature measuring devices **81** are preferably capable of measuring temperatures in the range of temperatures expected in the area of the wound **25**. More preferably, the temperature measuring devices **81** are capable of measuring temperatures in the range of 95 degrees Fahrenheit to 105 degrees Fahrenheit. The temperature measuring devices **81** may be any device that measures temperature in the desired range and produces a corresponding signal that may be interpreted by the alarm system **82** and temperature display and recording device **83**.

The temperature measuring devices **81** must, however, not be harmful to body tissue. The temperature measuring devices **81** are preferably thermocouples or optical sensors or detectors. The temperature measuring devices **81** are more preferably thermocouples that generate an electronic signal representing the temperature measured by the thermocouple.

The temperature measuring devices **81** are connected by leads **84** to an alarm system **82**. The leads **84** may be in any form compatible with the temperature measuring devices **81** and the alarm system **82** and recording device **83**. Preferably, the leads **84** are cables or wires constructed of an electrically conductive material, optical fiber, or other medium enabling data transmission that transfers the signals from the temperature measuring devices **81** to the alarm system **82** and the display and recording device **83**. Leads **84** placed under the wound cover **40** feedthrough the seal **42** beneath the cover **40** in a manner similar to that for the tubing (as illustrated and discussed above in connection with FIG. 1) that maintains the fluid impermeable nature of the seal **42**.

The alarm system **82** is comprised of a computer or other data processor **85** and an alarm device **86**. The computer or data processor **85** receives the signals from the temperature measuring devices **81** and converts them to electronic or other signals that are recognized by the alarm device **86**. The computer or data processor **85** is of a type that is commonly available in the relevant art. The alarm device **86** may produce any type of audible sound as an alarm, such as a ringing sound, buzzing, chirping or other common alarm noise. Alternatively, the alarm device **86** may include a digitally produced audible voice that presents predetermined messages corresponding to different temperature conditions in the area of the wound **25**. The alarm device **86** preferably produces different levels of alarm depending upon the temperature measurements received from the temperature measuring devices **81**. For example, as the temperature drops

below or rises above successive preselected values of temperature, as measured by any temperature measuring device **81**, the alarm device **86** may sound successive predetermined alarm pitches, sounds, messages or series of sounds. Similarly, as the temperature measured by multiple temperature measuring devices **81** successively falls below or rises above a preselected temperature, the alarm device **86** may sound successive predetermined alarm pitches, sounds, messages or series of sounds. The alarm system **82** may also be connected to the vacuum supply **50**, so that upon production of a predetermined alarm by the alarm device **86**, the vacuum pump controller **52** causes the pump **51** to cease operation.

The computer or data processor **85** may also be connected to a temperature display and recording device **83** that records the temperatures measured by one or more of the temperature measuring devices **81**. The temperature recording device **83** may be any device designed to record or display data that is compatible with the signals produced by the computer or data processor **85**. Such devices are preferably devices that record data on compact disks, floppy disks, magnetic tape, integrated circuits, or other similar media in digital form or "manual" devices that record or display data in a visually depicted form, such as a chart recorder or visual electronic display, such as an LCD or CRT monitor. The more preferred temperature display and recording device **83** is a device recording data on a compact disk used in conjunction with an LCD monitor.

It should be noted that in this embodiment of this version of the invention the cover **40** may be of any configuration, including the cover configuration illustrated in **FIG. 3** and the other cover configurations specifically discussed above in connection with **FIG. 3**. In addition, it is not necessary that any packing material or matrix **32** be present in the area of the wound **25** beneath the cover **40** in this version of the invention. It is also not necessary that the temperature

display and recording device **83** be included in every embodiment of this version of the invention. Nor is it necessary that the features included in this version of the invention be included as a part of any other version or embodiment of this invention.

In another version of the invention, the wound treatment apparatus **220** is portable and may be self-contained. In a first embodiment of this version of the invention, as illustrated in **FIG. 8a**, a miniature and portable vacuum source **250** is connected to a wound cover. The vacuum source **250** is preferably a miniature and portable vacuum pump. The vacuum source **250** may also be connected to a filter **253**, which is connected to a collection system **270**. The vacuum source **250** is used to provide suction to the reduced pressure appliance, generally designated as **230**. It is portable in the sense that it is of a size small enough to be positioned directly on the surface of the wound cover **240**. The vacuum source **250** is also lightweight to avoid placing too much pressure on any body part being treated by the apparatus **220** and to allow the apparatus **220** to be easily transported. The vacuum source **250** may be powered by electricity received through a cord plugged into a standard wall socket, or the vacuum source **250** may be powered by a battery, fuel cell, or other alternative means, such as solar or photo electric sells or a windmill or watermill operated generator. The vacuum source **250** may also be operated by other means, such as pneumatics or hydraulics, if such means are available.

The wound cover **240** may be of almost any size, shape, and configuration adapted to treat the wound. Thus, the wound cover **240** is not limited to the embodiment illustrated in **FIG. 8a**. As illustrated and discussed above in relation to **FIG. 3**, the cover may be comprised of a rigid, fluid impermeable, cone-shaped, bowl-shaped, or cup-shaped wound cover to protect the site of a wound **25** from impact or abrasion during treatment. Alternatively, the cover may be comprised of a flexible or rigid flat wound cover.

The vacuum source **250** may be attached to the cover **240** using any means that is compatible with the structure of the cover **240** and the vacuum source **250**. For example, if the cover **240** is constructed of a flexible, fluid impermeable material, the vacuum source **250** may be attached to the cover **240** using an adhesive material, such as a glue or other liquid or sprayed adhesive, adhesive tape, and similar means that are currently known in the relevant art or which may hereafter be discovered. As another example, if the wound cover **240** is constructed of a rigid material, the vacuum source **250** may be attached to the cover **240** using a variety of fasteners and similar means, such as anchors, bolts, rivets, screws, nuts, latch and clasp, hook and loop fasteners (such as that commonly sold under the trade name VELCRO), ultrasonic welding, and similar structures that are currently known in the relevant art or which may hereafter be discovered. The vacuum source **250** may therefore be permanently attached to the cover **240**, or the vacuum source **250** may be removably attached to the cover **240** allowing the vacuum source **250** to be reused after being used for a treatment even if the cover **240** is no longer usable after such treatment. The means of fastening the vacuum source **250** to the cover **240** must, however, be accomplished in a manner that allows the cover **240** to maintain the desired reduced pressure beneath the cover **240** while it is in use. Thus, gasket or sealant material may be used to seal any areas of perforation of the cover **240** where the fastener penetrates the surface of the cover **240**.

The fluid collection system **270** in the embodiment illustrated in **FIG. 8a** includes a container **271** to collect the exudate and a shutoff mechanism **275**, one embodiment of which is illustrated in **FIG. 8b**, to halt operation of the vacuum source **250** if the level of exudate in the container **271** exceeds a predetermined level. The container **271** is of the minimum size desired to collect and maintain the amount of exudate expected to be aspirated from the wound during

the time of anticipated use of the portable wound treatment apparatus **220**. Alternatively, a small container **271** may be used, in which the fluid is changed intermittently as necessary during the treatment period. The container **271** has two ports, a first port **272** for connecting the container **271** to the reduced pressure appliance **230** and a second port **273** for connecting the container **271** to the vacuum source **250**. A filter **253** may also be connected intermediate the vacuum source **250** and the container **271**. The shutoff mechanism may be comprised of any means that enables the vacuum system **250** to halt the supply of reduced pressure to the wound cover **240** at any time the volume of exudate from the wound exceeds a predetermined amount to prevent, thereby preventing such exudate from contaminating the vacuum source **250**. Such means may include mechanical switches, electrical switches operably connected to the vacuum source **250**, optical, thermal or weight sensors operably connected to the vacuum source **250**, and any other means that are currently known in the relevant art or which may hereafter be discovered. Where the shutoff mechanism transfers electrical or other data signals to the vacuum source **250**, the vacuum source **250** may contain a control mechanism to convert said signals to the form necessary to halt the production of reduced pressure by the vacuum source **250**. Such means is preferably the float valve shutoff mechanism **275** illustrated in **FIG. 8b**, connected to the second port **273** of the container **271**, which has the same features as the float valve illustrated in and discussed above in connection with **FIG. 4a**.

As illustrated in **FIG. 8a**, this embodiment of the invention may also include a filter **253** to prevent potentially pathogenic microbes or aerosols from contaminating the vacuum source **250**. The filter **253** is generally comprised of a filter element encased in a fluid impermeable housing that has an inlet port **256** and an outlet port **257**. The filter element is preferably a hydrophobic and micropore filter capable of filtering out pathogenic microbes or aerosols. The housing of the filter **253** may be constructed in a manner that enables the filter element to be

changed if desired. The filter **253** need not, however, be used in every embodiment of this version of the invention.

In the embodiment illustrated in **FIG. 8a**, tubing **245** is used to connect the reduced pressure appliance **230** covering a wound **225** to the collection system **270** by means of the first port **272** located on the container **271**. The features of this tubing **245** and reduced pressure appliance **230** are substantially the same as illustrated and discussed above in connection with **FIG. 1** and **FIG. 4a**. In addition, in the embodiment of the invention illustrated in **FIG. 8a**, the second port **273** of the container **271** is connected to the inlet port **256** of the filter **253** by flexible vacuum tubing **254**, such as that used to connect the collection system **270** to the reduced pressure appliance **230**. This is not, however, the only means of connecting the collection system **270** to the filter **253**. For example, the connection may be made by using a rigid, fluid impermeable structure, such as a short length of rigid polymer tube, permanently connecting the filter **253** and the collection system **270**. The filter **253** may also be directly attached to the container **271** without the use of any tubing or other means, causing the container **271** and the filter **253** to be integrated as a single unit. In the embodiment of the invention illustrated in **FIG. 8a**, the outlet port **257** of the filter **253** is connected to the vacuum source **250** by flexible vacuum tubing **254a**, such as that used to connect the collection system 270 to the reduced pressure appliance **230**. This is not, however, the only means of connecting the collection system **270** to the filter **253**. For example, the connection may be made by using a rigid, fluid impermeable structure, such as a short length of rigid polymer tube permanently connecting the filter **253** and the vacuum source **250**. The filter **253** may also be directly attached to the vacuum source **250** without the use of any tubing or other means, causing the container **271** and the filter **253** to be integrated as a single unit. As illustrated in **FIG. 8a**, the vacuum source **250**, the filter **253**, and the container **271** may also be directly attached to one

another to form a single integrated unit. Such attachment may be made by any of the means described above that may be used to attach the vacuum source **250** to the cover **240**.

Use of the wound treatment apparatus can be illustrated by a prospective example involving a reduced pressure appliance **30** of the type discussed in connection with **FIG. 1**. After preparing the bed of the wound **25**, one end of a length of vacuum tubing **45** is embedded in an absorbable matrix **32** that is trimmed to be the size and shape of the wound **25**. The matrix **32** is saturated with saline and placed in the wound **25**. As illustrated in **FIG. 7**, if temperature monitoring is desired, temperature measuring devices **81** are placed in the desired locations and connected to an alarm system **82**, and if desired, a display and recording device **83**. Alternatively, a temperature sensitive layer **80** is placed over the matrix, as illustrated in **FIG. 6**. A fluid impermeable or gas impermeable flexible adhesive sheet **40**, such as IOBAN, is placed over the matrix **32** (and temperature measuring means, if utilized) and the wound **25** and sealed to the normal skin **24** surrounding the wound **25**. The site of feedthrough of the vacuum tube **45** and any leads **84** from under the cover **40** is then sealed with a liquid or paste adhesive. Negative pressure is then applied to the reduced pressure appliance **30** by the vacuum system **50**, through the intermediate fluid collection system **70**.

Negative pressure appliances are useful for treating a variety of wounds. Treatment of a wound can be carried out by securing a negative pressure appliance to the treatment site as previously shown and described, and then maintaining a substantially continuous or cyclical reduced pressure within the appliance until the wound has reached a desired improved condition. A selected state of improved condition may include formation of granulation tissue sufficient for the attachment of a flap or graft, reduction of microbial infection in the wound, arrest or reversal of burn penetration, closure of the wound, integration of a flap or graft with the underlying

wounded tissue, complete healing of the wound, or other stages of improvement or healing appropriate to a given type of wound or wound complex.

It may be preferable to change the appliance periodically during treatment, particularly when using appliances incorporating a packing material on or in the wound. The time between changing the appliance where an absorbable matrix is placed on or in the wound would ordinarily be a greater time interval that is generally dependent upon the nature of the wound. Where it is necessary to change the absorbable matrix during the treatment period, it may also be necessary to remove a portion of the matrix, but leave in place the portion of the matrix into which there has been significant tissue growth. In such cases, the portion of the matrix without significant tissue growth incorporated therein should be carefully removed by cutting or tearing away such portion from the remaining portion. New absorbable material can be placed in the area from which the prior material has been removed.

The wound treatment apparatus is preferably operated using a negative or reduced pressure ranging from 0.01 to 0.99 atmospheres, and more preferably practiced using a negative or reduced pressure ranging between 0.5 to 0.8 atmospheres. The time period for use of the wound treatment apparatus on a wound may preferably be at least 12 hours, but can be, for example, extended for one or more days. There is no upper limit beyond which use of the wound treatment apparatus is no longer beneficial; use of the wound treatment apparatus increases the rate of closure up to the time the wound actually closes. Satisfactory treatment of various types of wounds has been obtained via the use of reduced pressures equivalent to about 2 to 7 in. Hg below atmospheric pressure.

Supplying reduced pressure to the appliance in an intermittent or cyclic manner has also

been demonstrated to be useful for treating wounds. Intermittent or cyclic supply of reduced pressure to an appliance may be achieved by manual or automatic control of the vacuum system 50. A cycle ratio, the ratio of "on" time to "off" time, in such an intermittent reduced pressure treatment may be as low as 1:10 or as high as 10:1. The preferred ratio is approximately 1:1 which is usually accomplished in alternating 5 minute intervals of reduced pressure supply and non-supply.

A suitable vacuum system 50 includes any suction pump capable of providing at least 0.1 pounds of suction to the wound, and preferably up to three pounds suction, and most preferably up to fourteen (14) pounds suction. The pump can be any ordinary suction pump suitable for medical purposes that is capable of providing the necessary suction. The dimension of the tubing interconnecting the pump and the reduced pressure appliance is controlled by the pump's ability to provide the suction level needed for operation. A 1/4 inch diameter tube may be suitable.

In treating damaged tissue, use of the invention usually comprises the steps of applying negative pressure to a wound for a selected time and at a selected magnitude sufficient to reduce bacterial density in the wound. Open wounds are almost always contaminated with harmful bacteria. The application of negative pressure to a wound appears to reduce the bacterial density of the wound. It is believed that this effect is due to either the bacteria's incompatibility with a negative pressure environment or the increased blood flow to the wound area, as blood brings with it cells and enzymes to destroy the bacteria.

Burns may generally be treated using a method that comprises the steps of applying negative pressure to the burn over an area with predetermined reduced pressure and for a time sufficient to inhibit formation of a full thickness burn. A partial thickness burn, one which has a

surface layer of dead tissue and an underlying zone of stasis, is often sufficiently infected so that it will transform within 24-48 hours into a full thickness burn, one in which all epidermal structures are destroyed. The application of negative pressure to the wound prevents the infection from becoming sufficiently severe to cause destruction of the underlying epidermal structures. The magnitude, pattern, and duration of pressure application can vary with the individual wound.